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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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10/788,747

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Kenneth W. Carpenter

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28213 7590 10/16/2008  
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EXAMINER

HELM, CARALYNNE E

ART UNIT

PAPER NUMBER

1615

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PAPER

**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

<b>Office Action Summary</b>	<b>Application No.</b> 10/788,747	<b>Applicant(s)</b> CARPENTER ET AL.	
	<b>Examiner</b> CARALYNNE HELM	<b>Art Unit</b> 1615	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

- 1) ☒ Responsive to communication(s) filed on 15 July 2008.
- 2a) ☐ This action is **FINAL**.                      2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

### Disposition of Claims

- 4) ☒ Claim(s) 1-67 is/are pending in the application.
- 4a) Of the above claim(s) 7-9, 16, 20-33, and 35-67 is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-6, 10-15, 17-19 and 34 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

### Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All    b) ☐ Some \*    c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

### Attachment(s)

- |  |   |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)            | 4) <input type="checkbox"/> Interview Summary (PTO-413)           |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)   | Paper No(s)/Mail Date. _____                                      |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date <u>12/19/07</u> .  | 6) <input type="checkbox"/> Other: _____                          |

Art Unit: 1615

## **DETAILED ACTION**

### ***Inventorship***

In view of the papers filed October 31, 2006, it has been found that this nonprovisional application, as filed, through error and without deceptive intent, improperly set forth the inventorship, and accordingly, this application has been corrected in compliance with 37 CFR 1.48(a). The inventorship of this application has been changed by the addition of Ramaz Katsarava.

The application will be forwarded to the Office of Initial Patent Examination (OIPE) for issuance of a corrected filing receipt, and correction of Office records to reflect the inventorship as corrected.

### ***Election/Restrictions***

Applicant's election of Group I and the species where aminoxyls are the bioactive agent and a polypeptide of 2 to about 25 amino acids as the linker in the reply filed on July 15, 2008 is acknowledged. Because applicant did not distinctly and specifically point out the supposed errors in the restriction requirement, the election has been treated as an election without traverse (MPEP § 818.03(a)).

The restriction is still deemed proper and thereby made FINAL.

Claims 7-9, 16, 20-33, and 35-67 are withdrawn from further consideration pursuant to 37 CFR 1.142(b) as being drawn to a nonelected inventions and species, there being no allowable generic or linking claim.

Art Unit: 1615

***Claim Rejections - 35 USC § 112***

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claim 19 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

The phrase “by about 5 angstroms to about 200 angstroms” in claim 19 is a relative phrase, which renders the claim indefinite. The phrase “by about 5 angstroms to about 200 angstroms” is not defined by the claim, the specification does not provide a standard for ascertaining the requisite degree, and one of ordinary skill in the art would not be reasonably apprised of the scope of the invention. The phrase “by 5 angstroms to 200 angstroms” typically indicates a minimum and maximum point. However, the phrase “by 5 angstroms to 200 angstroms” is controverted by the term “about” which implies that values above and below both 5 angstroms and 200 angstroms are permitted. Further, the extent of variance permitted by “about” is unclear in the context. Therefore it is unclear whether “about 5 angstroms” simply includes a small deviation (e.g. 10%-20%) or if a larger deviation (e.g. 25%-100%) is included as well. A similar amount of deviation is possible for 200 angstroms. Thus the interpretation of the phrase “by about 5 angstroms to about 200 angstroms” in this context is unclear as no definitive upper and lower bound can be defined.

***Claim Rejections - 35 USC § 103***

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

Art Unit: 1615

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

The four factual inquiries of *Graham v. John Deere Co.* have been fully considered and analyzed in the rejections that follow.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

Claims 1-6, 10-15, 17-19, and 34 are rejected under 35 U.S.C. 103(a) as being unpatentable over Chu et al. (WO 02/18477) in view of Lang et al. (US Patent No. 6,830,747).

Chu et al. teach a drug (bioactive agent) containing biodegradable polymer coating (see page 2 lines 21-26 and 12 lines 3-13; instant claim 1). These drugs are taught to be connected to the polymer via a linker such that upon degradation, the active drug is released (see page 42 lines 1-3; instant claim 2). The polymers of their invention are taught as being applied to the

Art Unit: 1615

surface of a medical device, where a vascular stent is particularly envisioned (see page 43 lines 1-3 and 9-12; instant claims 1 and 34). Chu et al. go on to teach particular components in the polymer as well as drugs and linker molecules that are used. The linker is taught to separate the drug from the polymer by 5 angstroms to 200 angstroms and be composed of 2 to about 25 amino acids (see page 39 lines 4-7 and 11-13; instant claims 15, 17, and 19). Such a polypeptide chain is envisioned as poly-L-lysine, poly-L- glutamic acid, poly-L-aspartic acid, poly-L-histidine, poly-L-ornithine, poly-L-threonine, poly-L-tyrosine, poly-L-leucine, poly-L-lysine-L-phenylalanine, poly-L-arginine, or poly-L- lysine-L-tyrosine (see page 40 lines 16-22; instant claim 18). A variety of drugs are taught where the aminoxyl, 4-amino-2, 2, 6, 6,-tetramethylpiperidinyloxy, is exemplified (see example 25; instant claims 3-6 and 10-11). The polymer is taught to be a polyester amide (see page 45 lines 3-4; instant claim 12). Chu et al. do not teach that polycaprolactone is the polyester in the taught polymer.

Lang et al. teach modified polyester amide polymers that also have the drug 4-amino-2, 2, 6, 6,-tetramethylpiperidinyloxy attached to the polymer chain (see column 3 lines 33-62 and columns 7-8, 5<sup>th</sup> row of the exemplified reaction; instant claims 12-14). This exemplified polymer is a copolymer of polycaprolactone with polylactide, where acrylic acid is the linker between the polymer and the drug. This drug containing polymer is also taught to be used as a coating on a stent (see column 13 lines 7-13; instant claim 1). Since both Lang et al. and Chu et al. teach the same type of drug modified polymers on the stent, where the same drug is attached via a linker, it would have been obvious to one of ordinary skill in the art at the time the invention was made to use the polycaprolactone-polylactide copolymer taught by Lang as the polymer in the polymer coating preparation of Chu et al. Therefore claims 1-6, 10-15, 17-19, and 34 are obvious over Chu et al. in view of Lang et al.

Art Unit: 1615

***Double Patenting***

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. A nonstatutory obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but at least one examined application claim is not patentably distinct from the reference claim(s) because the examined application claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., *In re Berg*, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) or 1.321(d) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent either is shown to be commonly owned with this application, or claims an invention made as a result of activities undertaken within the scope of a joint research agreement.

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

Claims 1-6, 10-11, 15, and 19 are provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1, 16-17, and 32 of copending Application No. 11/098891. Although the conflicting claims are not identical, they are not patentably distinct from each other because both claim a stent with a biodegradable, bioactive polymer where the bioactive, an aminoxyl, is covalently attached to the polymer via a linker that separates the bioactive from the polymer by about 5 angstroms to about 200 angstroms.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

Claims 1-6, 10-11, 15, 17-19, and 34 are provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1-6, 14, 25, 28-29, and 31 of copending Application No. 11/345815, claims 1-6, 25, 27-29, and 31 of

Art Unit: 1615

copending Application No. 11/128903, and claims 1-6, 25, 27-29, and 31 of copending Application No. 11/147994, in view of Chu et al. Although the conflicting claims are not identical, they are not patentably distinct from each other because both claim a stent with a biodegradable, bioactive polymer where the bioactive, an aminoxyl, is covalently attached to the polymer via a linker. These copending application do not teach a polypeptide as the linker where it separates the bioactive from the polymer by about 5 to about 200 angstroms.

Chu et al. teach a drug (bioactive agent) containing biodegradable polymer coating (see page 2 lines 21-26 and 12 lines 3-13). These drugs are taught to be connected to the polymer via a linker such that upon degradation, the active drug is released (see page 42 lines 1-3). The linker is taught to separate the drug from the polymer by 5 angstroms to 200 angstroms and be composed of 2 to about 25 amino acids (see page 39 lines 4-7 and 11-13; instant claims 15, 17, and 19). In view of these teachings it would have been obvious to one of ordinary skill in the art to use the particular linker molecules taught by Chu et al. in the inventions of the copending applications.

These are provisional obviousness-type double patenting rejections.

### ***Conclusion***

No claim is allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to CARALYNNE HELM whose telephone number is (571)270-3506. The examiner can normally be reached on Monday through Thursday 8-5 (EDT).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael Woodward can be reached on 571-272-8373. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.



Art Unit: 1615

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Caralynne Helm/  
Examiner, Art Unit 1615

/MP WOODWARD/  
Supervisory Patent Examiner, Art Unit 1615